

Latest Packaging & Shipping Regulation Updates

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Since the 2005 release of its Dangerous Goods Regulations (DGR), the International Air Transport Association (IATA) has issued 4 addenda to the DGR. Because the U.S. Department of Transportation (DOT) is expected to change its regulations to match those of IATA, those responsible for packaging and shipping infectious substances should take note of the following updates.

Because these regulations are constantly changing, it is the shipper's responsibility to be aware of changes in order to stay in compliance with current regulations. You are responsible to ensure that your specimens are properly packaged. Take the time to pack your specimens carefully and correctly.

IATA Updates: If you ship anything by air, you must follow current IATA guidelines (available for purchase online at www.iata.org/ps/publications). As of January 2005, IATA changed its classification and labeling requirements so that infectious substances are divided into Categories A and B.

Category A infectious substances are those that are transported in a form that, if exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. Table 1 provides a list of infectious substances that must be assigned to Category A. Note that rabies virus is only assigned to Category A when it is shipped as a culture. You should use the IATA Packing Instructions 602 for Category A materials.

Infectious substances that cause disease in humans or in both humans and animals must be assigned the United Nations number UN 2814. Infectious substances that cause

disease only in animals are assigned to UN 2900. These numbers are used on the Shipper's declaration and outer package labeling. The proper shipping name for UN 2814 is "Infectious substance, affecting humans." The proper shipping name for UN 2900 is "Infectious substance, affecting animals only."

Assignment to UN 2814 or UN 2900 is based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgment concerning individual circumstances of the source human or animal.

If you don't know what the pathogen is and suspect that it might be a Category A pathogen, you can use IATA's Special Provision 140 that allows you to list as the proper shipping name "Suspected Category A infectious substance."

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

Anemia	PAP Smear
ANA	Point-of-Care Testing
Bioterrorism Event Mgmt	PSA
Bleeding Disorders	Rash Illness
Chlamydia	Red Cell Transfusion
Diabetes	Renal Disease
Group A Strep Pharyngitis	STD
Hepatitis	Thyroid
HIV	Tuberculosis
Infectious Diarrhea	Urinalysis
Intestinal Parasites	Wellness
Lipid Screening	

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Table 1. Category A Infectious Substances*

UN 2814 - Infectious substances affecting humans or both humans and animals.

Micro-organisms (cultured only)

- *Bacillus anthracis*
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*
- *Burkholderia mallei* – *Pseudomonas mallei* – *Glanders*
- *Burkholderia pseudomallei* – *Pseudomonas pseudomallei*
- *Chlamydia psittaci* – avian strains
- *Clostridium botulinum*
- *Coccidioides immitis*
- *Coxiella burnetii*
- Dengue virus
- Eastern equine encephalitis virus
- *Escherichia coli*, verotoxigenic
- *Francisella tularensis*
- Hepatitis B virus
- Herpes B virus
- Highly pathogenic avian influenza virus
- Human immunodeficiency virus
- Japanese Encephalitis virus
- *Mycobacterium tuberculosis*
- Poliovirus
- Rabies virus
- *Rickettsia prowazekii*

- *Rickettsia rickettsii*
- Rift Valley fever virus
- Russian spring-summer encephalitis virus
- *Shigella dysenteriae* type
- Tick-borne encephalitis virus
- Venezuelan equine encephalitis virus
- West Nile virus
- Yellow fever virus
- *Yersinia pestis*

Micro-organisms (in any form, cultured or uncultured)

- Crimean-Congo hemorrhagic fever virus
- Ebola virus
- Flexal virus
- Guanarito virus
- Hantaan virus
- Hantavirus causing hemorrhagic fever with renal syndrome
- Hendra virus
- Junin virus
- Kyasanur Forest disease virus
- Lassa virus
- Machupo virus
- Marburg virus
- Monkeypox virus
- Nipah virus
- Omsk hemorrhagic fever virus
- Sabia virus
- Variola virus

UN 2900 Infectious substances affecting animals only

Micro-organisms (cultured only)

- African swine fever virus
- Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus
- Classical swine fever virus
- Foot and mouth disease virus
- Goatpox virus
- Lumpy skin disease virus
- *Mycoplasma mycoides* – Contagious bovine pleuropneumonia
- Peste des petits ruminants virus
- Rinderpest virus
- Sheep-pox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus

* This list is not a complete list.

Category B infectious substances are simply defined as those that do not meet the criteria for inclusion in Category A. These are specimens collected for diagnostic purposes that are known to contain a treatable or preventable infectious substance. An example of this would be blood collected from a person infected with HIV for cholesterol testing purposes or sputum collected for TB testing. You should use IATA Packing Instructions 650 for Category B materials. Infectious substances in Category B are assigned to UN 3373.

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PHL home page: <http://www.doh.wa.gov/EHSPHL/PHL/default.htm>

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The current proper shipping name for Category B substances is Diagnostic specimen, Clinical specimen or Biological substance, Category B. On January 1, 2007, IATA will stop accepting the use of "Diagnostic specimen" and "Clinical specimen" so the only acceptable shipping name will be "Biological substance, Category B".

Exemptions: Infectious substances or patient specimens must be assigned as either UN 2814, UN 2900, or UN 3373 as appropriate, except if they comply with the following exemptions and do not fit the criteria for inclusion in another class of hazardous material:

- Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals.
- Substances containing microorganisms that are non-pathogenic to humans or animals.
- Substances in any form such that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk.
- Environmental samples (including food and water samples) which are not considered to pose a significant risk of infection.
- Dried blood spots, collected by applying a drop of blood onto absorbent material, or fecal occult blood screening tests and blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation.

Examples of specimens which may be transported under these exemptions include routine blood or urine tests from humans or animals with non-infectious diseases and biopsy/tissue specimens.

Patient specimens are not subject to IATA regulations as long as the specimen is properly packaged to prevent any leakage, and the package is marked with the words "Exempt human specimen" or "Exempt animal specimen" as appropriate. The packaging must meet the following conditions:

- Packaging must consist of three components:
 1. A leak-proof primary receptacle(s);
 2. A leak-proof secondary packaging; and
 3. An outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100mm x 100mm.
- For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material.

- When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

DOT Updates: The DOT is still using Risk Group categories, but it has issued a proposed ruling to harmonize with IATA regulations. This means that DOT will use the Category A and Category B classification instead of Risk Groups. Current DOT regulations stipulate using "diagnostic specimen" and not "clinical specimen." The DOT is expected to phase out the use of "diagnostic specimen" as a proper shipping name and replace it with "Biological substance, category B" as part of its harmonization with IATA. The final ruling should be issued by the end of 2005.

USPS Updates: For those of you who ship specimens through the U.S. Postal Service (which does not fall under DOT regulations), you must still classify infectious specimens according to Risk Group (1, 2, 3 or 4). The USPS regulations are being updated, however, and are expected to harmonize with international rules as set forth in the IATA DGR. However, the USPS will still limit quantities of Category A infectious material to 50ml or 50g per mail piece.

Couriers: Despite the fact that couriers don't fall under these regulations, you should still package your specimens well enough to minimize the risk of spills and exposure to potential pathogens. We recommend that labs use triple packaging even for couriers. In the event of an accident or if somehow the external package becomes compromised, there will still be a secondary package to provide protection. Ensure that the secondary container has enough absorbent material to soak up any liquid resulting from a spill or breakage. Also make sure that you have properly labeled your specimens and included a list of contents. The list of contents should be attached to the outside of the secondary container.

Remember, it is your job as the shipper to ensure that your specimens are properly packaged. Take the time to pack your specimens carefully and correctly.

Packaging & Shipping Classes to help you comply with the regulations

November 15, 2005 – Tacoma, WA
December 2, 2005 – Shoreline, WA

Future classes will be listed in the
"Calendar of Events" box on the last page of each
Elaborations newsletter or visit the following website:
<http://www.doh.wa.gov/EHSPHL/PHL/train.htm>

12th Annual Clinical Laboratory Conference

November 7, 2005
8:00 a.m. - 4:30 p.m.

Seattle Marriott Hotel at SeaTac
International Airport

If you have not received a copy of the program,
contact Leonard Kargacin:
phone: (206) 418-5416,
e-mail: leonard.kargacin@doh.wa.gov

The program is also available from the LQA website:
http://www.doh.wa.gov/hsqa/fsl/lqa_updates.htm.

Calendar of Events

PHL Training Classes:

(<http://www.doh.wa.gov/EHSPHL/PHL/train.htm>)

Gram Stain: A Practical Approach

November 9 Shoreline

Northwest Medical Laboratory Symposium

October 26-29, 2005 Seattle

12th Annual Clinical Laboratory Conference

November 7, 2005 Seattle

2006 WSSCLS/NWSSAMT Spring Meeting

April 20-22, 2006 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.